



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

2012 Parenteral Drug Association/Food and Drug Administration Joint Regulatory Conference;  
Compliance Through Quality Systems: Implementing and Advancing a Sustainable Global  
Quality Culture

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

Summary: The Food and Drug Administration (FDA), in cosponsorship with Parenteral Drug Association (PDA), is announcing a public conference entitled “Compliance Through Quality Systems: Implementing and Advancing a Sustainable Global Quality Culture.” The conference will cover current issues affecting the industry as well as explore strategies and approaches for ensuring conformance with regulations to facilitate the development and continuous improvement of safe and effective medical products. The conference establishes a unique forum to discuss the foundations, emerging technologies and innovations in regulatory science, as well as the current quality and compliance areas of concerns. Meeting participants will hear from FDA and industry speakers about the requirements and best practices to consider while implementing robust quality systems in order to deliver the best quality product.

Date and Time: The public conference will be held on September 10, 2012, from 7 a.m. to 6 p.m.; September 11, 2012, from 7:30 a.m. to 6:15 p.m.; and September 12, 2012, from 7:30 a.m. to 12:15 p.m.

Location: The public conference will be held at the Baltimore Marriott Waterfront Hotel, 700 Aliceanna St., Baltimore, MD 21202, 410-385-3000, FAX: 410-895-1900.

Contact: Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 200, Bethesda, MD 20814, 301-656-5900, ext. 111, FAX: 301-986-1093, email: [info@pda.org](mailto:info@pda.org).

Accommodations: Attendees are responsible for their own accommodations. To make reservations at the Baltimore Marriott Waterfront Hotel at the reduced conference rate, contact the Baltimore Marriott Waterfront Hotel (see Location)--cite the meeting code “PDA.” Room rates are: Single: \$229, plus 15.5 percent state and local taxes and Double: \$229, plus 15.5 percent state and local taxes. Reservations can be made on a space and rate availability basis.

Registration: Attendees are encouraged to register at their earliest convenience. The PDA registration fees cover the cost of facilities, materials, and refreshments. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted for the conference will receive confirmation. Registration will close after the conference is filled. Onsite registration will be available on a space available basis on each day of the public conference beginning at 7 a.m. on September 10, 2012. The cost of registration is as follows:

Table 1.--Cost of Registration

Affiliation	Through August 10, 2012	After August 10, 2012
Member	\$1,700	\$1,900
Nonmember	\$1,949	\$2,149
Government/Health Authority Member	\$530	\$530
Government/Health Authority Nonmember <sup>1</sup>	\$700	\$700
Academic Member	\$700	\$700
Academic Nonmember <sup>1</sup>	\$800	\$800

Table 1.--Cost of Registration

Affiliation	Through August 10, 2012	After August 10, 2012
Student Member	\$280	\$280
Student Nonmember <sup>1</sup>	\$310	\$310

<sup>1</sup>Applicable nonmember rates

Please visit PDA's Web site: <http://www.pda.org/pdafda2012> to confirm the prevailing registration fees. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Website after this document publishes in the Federal Register.)

If you need special accommodations due to a disability, please contact Wanda Neal (see Contact), at least 7 days in advance of the conference.

Registration Instructions: To register, please submit your name, affiliation, mailing address, telephone, fax number, and email address, along with a check or money order payable to “PDA.” Mail to: PDA, Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 200, Bethesda, MD 20814. To register via the Internet, go to PDA's Web site: <http://www.pda.org/pdafda2012>.

The registrar will also accept payment by major credit cards (VISA/American Express/MasterCard only). For more information on the meeting, or for questions on registration, contact PDA (see Contact).

Transcripts: As soon as a transcript is available, it can be obtained in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The PDA/FDA Joint Regulatory Conference offers the unique opportunity for participants to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on current efforts affecting the

development of global regulatory strategies, while industry professionals from some of today's leading pharmaceutical companies present case studies on how they employ global strategies in their daily processes.

Through a series of sessions and meetings, the conference will provide participants with the opportunity to hear directly from FDA experts and representatives of global regulatory authorities on best practices, including:

- Regulatory Submission and Meetings
- Quality Risk Management Implementation
- Manufacturing in the Future
- Quality Systems
- Regulatory Considerations During Development
- Cell Therapy Innovations
- Life Cycle Management
- Process Validation
- Validation FDA Guidance
- Challenges of Contract Manufacturing Organizations
- Contract Agreements
- Drug Safety
- Emerging Active Pharmaceutical Ingredients (API) Regulations
- Investigations
- Emerging API Regulations
- User Fees
- Excipient Best Practices

- Good Manufacturing Practices Foreign Inspections Findings
- Regulatory Process to Approval (Inspectional Readiness)
- Combination Products and Companion Diagnostics

To help ensure the quality of FDA-regulated products, the workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as outreach activities by Government Agencies to small businesses.

Dated: August 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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